

Message

From: Dourson, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BB29BF491D9A4C3AB569022BCD205A0A-DOURSON, MI]
Sent: 10/31/2017 11:15:07 PM
To: Beck, Nancy [beck.nancy@epa.gov]
Subject: RE: FQPA safety factors

Nancy

Well perhaps we need to talk to some of our OPP colleagues to get a sense of how often FQPA is invoked when the database uncertainty factor is not needed. My sense would be seldom if ever, since the judgment that the DB UF is not needed is because we have reliable data.

Mike

From: Beck, Nancy
Sent: Tuesday, October 31, 2017 11:00 AM
To: Dourson, Michael <dourson.michael@epa.gov>
Subject: FW: FQPA safety factors

Mike—

See attached and below.

The key, to me, is what is “reliable data”. The 2002 documents (see attached) help with that, a bit.

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Deputy Assistant Administrator, OCSPP
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Ex. 6 Personal Privacy (PP)

beck.nancy@epa.gov

From: Keller, Kaitlin
Sent: Tuesday, October 31, 2017 10:53 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Subject: FQPA safety factors

Nancy,

These are the two guidance documents linked from the EPA 10x safety factor page. If you think there's something more recent let me know and I'll get it from OPP.

On a somewhat related note, I've also attached the 2016 CLA petition on epi studies—this was one of the follow-up requests from the OP briefing for Charlotte & Mike last week so I'm just compiling that here.

More on the legal text on 10x and the different uncertainty factors we use is pulled from the documents below. I'm still sifting the interwebs for the actual FFDCA Section 408 text.

Thanks,
Kaitlin

The portion of FFDCA section 408 addressing exposure of infants and children to pesticide chemical residues, section 408(b)(2)(C), directs that EPA, in taking action regarding a tolerance, “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.” Section 408(b)(2)(C)(ii)(I). This paragraph also explicitly requires EPA to assess the risk to children taking into account “available evidence concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity.” Section 408(b)(2)(C)(i)(III). Finally, this paragraph mandates that, in making the reasonable certainty of no harm finding, EPA apply an additional tenfold margin of safety to take into account potential pre- and postnatal toxicity and completeness of the toxicity and exposure databases. A different factor may be applied if the safety finding is supported by reliable data. This is referred to as the “FQPA safety factor” provision.

To capture both the standard and traditional aspects as well as the uniqueness of the FQPA safety factor, EPA has chosen to use the following terminology to describe the two components of the FQPA safety factor:

- ☐ Standard uncertainty factors are the 10X factors used to account for interhuman variation (intraspecies differences-UFH) and experimental animal to human (interspecies-UFA) differences. These uncertainty factors are not considered to be FQPA safety factors.
- ☐ Traditional uncertainty factors are those used prior to FQPA passage to account for database deficiencies (i.e., application of an uncertainty factor to extrapolate from subchronic to chronic data (UFS) if deriving a chronic RfD); application of an uncertainty factor to extrapolate from the NOAEL to LOAEL (UFL) if no appropriate NOAEL can be identified in the toxicology database; and application of a database uncertainty factor (UFDb) which is intended to account for the absence of key toxicological data) and which are now codified by FQPA; and
- ☐ Special FQPA safety factors are used to apply to the aspect of a different FQPA factor (i.e., residual concerns for susceptibility and residual concerns in the exposure assessment) that is unique to FQPA, and which are those factors introduced primarily as a result of FQPA.